

**REMARKS**

This amendment is responsive to the Office Action mailed October 18, 2003. Following entry of the instant amendment claims 1-5 stand amended, claims 6-13 stand cancelled and new dependent claims 14-24 (which depend directly or indirectly from amended claim 1) stand ready for examination on the merits.

Applicants respectfully solicit entry of and favorable consideration of the amendments and remarks set forth herein.

New claims 14-18 closely correspond to the subject matter of claims 1-6 except they are set forth in method claim format. New claim 19 is directed to instructions for performing the present computer-implemented invention, as stored on a computer readable medium. Adequate support for the newly presented claims is found in the specification of the application (and the prior provisional application) as well as via principles of inherency, given the nature of the subject matter claimed.

Thus, claims 1-5 and 14-24 are presented for examination on the merits.

**Claim Rejection Under 35 U.S.C. § 102**

In the Office Action, the Examiner rejected claims 1, 2, 4 and 5 under 35 U.S.C. § 102(b) as being anticipated by Tockman et al. *but has perhaps inadvertently cited U.S. Pat. No. 5,562,707 – which issued to Prochazka et al.* Since the passages recited in the Office Action in support of the rejection comport with the content of U.S. Pat. No. 5,540,727 to Tockman et al. (Tockman), Applicants herein treat the rejection as based entirely upon Tockman.

In particular, the Examiner asserted that Tockman teaches a method and apparatus to automatically optimize the pacing mode and the pacing cycle parameters of an implantable stimulating device using an optimization sequence, read as providing a dynamic closed loop self-monitoring system. According to the Examiner, the apparatus comprises a pacemaker, a micro-controller, a radio frequency (RF) telemetry link, and external sensors/monitors, including an oximeter.

Applicants respectfully traverse the rejection to the extent such rejection may be considered applicable to the amended claims.

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"A single prior art reference anticipates a patent claim if it expressly or inherently describes each and every limitation set forth in the patent claim." Trintec Indus. Inc. v. Top-U.S.A. Corp., 63 USPQ2d 1597, 1599 (Fed. Cir. 2002). "Inherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art." Id. Tockman fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that suggests the desirability of modification to include such features.

Tockman does not disclose an external sensor module *continuously* transmitting *continuously* collected physiological data signals to an IMD, as recited in claim 1. On the contrary, Tockman discloses transmitting "operating parameters" to the IMD or programming to the IMD. Col. 3, lines 62-65; col. 5, lines 12-14; col. 6, lines 54-58. In particular, a programmer 42 receives signals from various sensors 44-52, but Tockman does not disclose or suggest continuously transmitting those sensor signals to the IMD via telemetry link 40.

Furthermore, Tockman does not teach or suggest that a processor in the IMD processes physiological data collected by an external sensor, as recited in claim 1. Instead, Tockman discloses the IMD receiving "operating parameters" or programming from programmer 42. Col. 3, lines 62-65; col. 5, lines 12-14; col. 6, lines 54-58.

Moreover, contrary to the assertion of the Examiner at page 3 of the Office Action, FIG. 2 does not depict or support (at 56) the notion that "sensor data enters the 'software' of the implanted device microprocessor." In fact, as described at col. 5, ll. 12-18 that "[t]he entry of these *user inputs* is indicated by block 56 in FIG. 2." (emphasis added.) As depicted at FIG. 2 of Tockman, such user inputs exclusively includes merely pacing intervals such as an initial, maximum atrio-ventricular (AV) delay interval, AV increments and the like.

Tockman also fails to teach or suggest the IMD processor processing the physiological data to produce therapy delivery control signals in implementation of dynamic closed loop self monitoring therapy delivery, as recited in independent claims 1, 14 and 19. The Tockman implanted device does not continuously receive physiological data, and consequently the Tockman implanted device does not process

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physiological data in implementation of a dynamic, closed-loop, self-monitoring therapy delivery, as recited in claims 1, 14 and 19.

In view of the differences identified above, Tockman clearly fails to anticipate the features set forth in claims 1, 2, 4 and 5. For at least these reasons, the Examiner has failed to establish a *prima facie* case for anticipation of Applicants' claims 1, 2, 4 and 5 under 35 U.S.C. § 102(b). Withdrawal of these rejections is respectfully requested.

In addition, as a matter of convenience only Applicants herewith presents minor amendments to claims 2-5 (e.g., claim 2 stands amended to recite that the IMD comprises a pacemaker only in lieu of the former *Markush* group). Applicants respectfully assert that these minor amendments were added for convenience and not for any reason related to patentability and that, in any event, said amendments do not constitute narrowing amendments.

#### Claim Rejection Under 35 U.S.C. § 103

*Tockman in view of Kopotic et al. (U.S. Pat. No. 6,470,199)*

In the Office Action, the Examiner rejected claim 3 under 35 U.S.C. § 103(a) as being unpatentable over Tockman (US 5,540,727) in view of Kopotic. According to the Examiner, Tockman discloses the claimed invention as described hereinabove except for providing an external sensor module in the configuration of a sock.

Applicants respectfully traverse the rejections and hereby incorporate the above remarks with respect to Tockman as if fully set forth herein. In connection with combining references to support an assertion of obviousness, it is well established that the Examiner bears the burden of establishing a *prima facie* case of obviousness. *In re Oetiker*, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). In doing so, the Examiner must determine whether the prior art provides a "teaching or suggestion to one of ordinary skill in the art to make the changes that would produce" the claimed invention. *In re Chu*, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995). A *prima facie* case of obviousness is established only when this burden is met.

In the case of *In re Lee*, 61 USPQ2d 1430 (Fed. Cir. 2002), the Federal Circuit stated: "This factual question of motivation is material to patentability, and [can] not be resolved on subjective belief and unknown authority." *Id.* at 1434.

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The Court of Appeals for the Federal Circuit has made clear that motivation to combine references must be found in the record, and that it is impermissible hindsight for the Examiner to use the motivation stated in Applicants' own disclosure as a blueprint to reconstruct the claimed invention from the prior art. See Interconnect Planning Corp. v. Feil, 227 USPQ 543 (Fed. Cir. 1985); In re Fine, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); In re Gorman, 18 USPQ 2d 1885, 1888 (Fed. Cir. 1991); Al-Site Corp. v. VSI International, Inc., 50 USPQ2d 1161, 1171 (Fed. Cir. 1999).

A patentable invention may arise from a combination of elements found in the prior art. It is therefore not sufficient for the Examiner merely to identify individual components of an invention in multiple references. E.g., Ruiz v. A.B. Chance Co., 57 USPQ2d 1161, 1167 (Fed. Cir. 2000). The Examiner must demonstrate that a skilled artisan, with no knowledge of Applicants' claimed invention, would have selected the components for combination in the manner claimed. In re Kotzab, 55 USPQ2d 1313, 1316-18 (Fed. Cir. 2000). It is not sufficient for the Examiner to assert that separate elements of the claimed invention exist in the prior art, or that the elements in different references *could* be combined, or that there is an apparent need for combination of the elements, or that elements may be substitutes for one another. Ruiz v. A.B. Chance Co., 57 USPQ2d at 1167. To establish a *prima facie* case of unpatentability, the Examiner must provide evidence showing a reason, suggestion or motivation to combine.

The Examiner has failed to provide evidence showing a reason, suggestion or motivation to combine a system according to Tockman with a sensor according to Kopotic. Applicants respectfully assert that no support exists for the asserted combination of these two references. Nothing in the references suggests the presently claimed combination.

The Examiner's assertion that changing the type of sensor would have been an "obvious design choice" is incorrect as a matter of law. First, it applies an incorrect legal standard. In a proper obviousness determination, the prior art must give a reason or motivation for making the claimed invention. E.g., In re Chu, 36 USPQ2d at 1094; In re Oetiker, 24 USPQ2d at 1446. The combination of elements from non-analogous sources, in a manner that reconstructs the Applicants' invention only with the benefit of

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hindsight, is insufficient to support a *prima facie* case of obviousness. In re Oetiker, 24 USPQ2d at 1446. Where the prior art does not teach that references should be combined to produce the claimed invention, the Examiner cannot cure this deficiency by using words such as "design choice" or "design alternative." In re Chu, 36 USPQ2d at 1094-95. A bare assertion that an element of a claim is an "obvious design choice" does not support a *prima facie* case of unpatentability. It is merely a conclusory statement, unsupported by the record, and cannot support a *prima facie* case of unpatentability. In re Lee, 61 USPQ2d at 1434-35; In re Dembicza, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

For at least these reasons, the Examiner has failed to establish a *prima facie* case for non-patentability of Applicants' claim 3 under 35 U.S.C. § 103(a). Withdrawal of these rejections is respectfully requested.

### CONCLUSION

Applicants respectfully assert that, following entry of the instant Amendment, all pending claims (i.e., claims 1-5 and 14-24) of the present application are in condition for allowance. Applicants respectfully request reconsideration and prompt allowance of all pending claims so that the invention herein claimed may pass to timely issuance as U.S. Letters Patent. Please charge any additional fees or credit any overpayment to deposit account number 13-2546. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Respectfully submitted,



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